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Food Safety And Inspection Service
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AUDIT REPORT FOR HUNGARY

FEBRUARY 12 THROUGH FEBRUARY 28, 2002

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Hungary's meat inspection system February 12 through February 28, 2002. All seven establishments certified to export meat product to the United States were audited. Six of these were slaughter and processing establishments; one was processing only.

The last audit of Hungary's inspection system was conducted in November 2000. Six establishments were audited (Ests. 5, 6, 7, 10, 24, and 62). The auditor found significant problems in one establishment (Est. 5) that was then designated as marginal/re-review at the next audit. Major concerns reported at that time:

1. In Establishments 5, 10, 24 and 62, loose plastic strands were observed in plastic product containers.
2. There was no sanitary procedures in place to re-condition incidentally dropped meat in all establishments.
3. Establishment 5 did not identify product contact equipment to be monitored during pre-operational sanitation. Effectiveness of sanitation standards operating procedures (SSOPs) was not monitored by official inspectors.
4. *Listeria monocytogenes* as hazard likely to occur in ready-to-eat (RTE) products was not considered in Hazard Analysis Critical Control Plan (HACCP) in all establishments and there was no official policy/requirements for *Listeria* positive samples.
5. Species identification monitoring was not being done in Ests.5 and 24, and on-going species verification testing program was not documented.
6. In Establishment 5, inspection coverage was not provided during the second/night shift.
7. Other concerns included inadequate denaturing/decharacterization of inedible and condemned product.

The auditor verified that all of the above deficiencies had been corrected and all establishments operate only one shift according to Government of Hungary officials.

At the time of this audit, Hungary was eligible to export processed pork and beef products to the United States (U.S.).

During calendar year 2001, Hungarian establishments exported 4,215,865 pounds of cured pork, and pasteurized canned hams and picnics to the U.S. There was no rejection of products at the port of entry inspection during this period.

PROTOCOL

The on-site review was conducted in three parts. One part involved visits with Hungarian national meat inspection officials at Budapest headquarters to discuss oversight programs and practices, including enforcement activities. The second part entailed on-site audits of seven establishments certified for export to U.S. The third part was visit to two laboratories, one performing analytical testing of field samples for the national residue testing program, and the other culturing field samples for the presence microbiological contamination with *Salmonella.*

Hungary's program effectiveness was assessed by evaluating five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOPs), (2) animal disease controls, (3) residue controls, (4) slaughter/processing controls, including the implementation of Hazard Analysis and Critical Control Point (HACCP) systems, and the *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species.

During all on-site establishment visits, the auditor evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditor also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the U.S., and are delisted accordingly by the country's meat inspection officials.

RESULTS AND DISCUSSION

Summary

Effective inspection controls were found to be in place in all seven establishments audited (Ests. 5, 6, 7, 10, 24, 62, and 147) except as noted later in this report. Details of audit findings, including compliance with HACCP, SSOP, and testing programs for *Salmonella* and generic *E. coli,* are discussed later in this report.

The last audit of the Hungary's meat inspection system was conducted in November 2000. During this new audit, the auditor determined that the concerns had been addressed and corrected.

Entrance Meeting

On February 12, 2002, an entrance meeting was held at the Hungary's Ministry of Agriculture, Department of Animal Health and Food Control headquarters, and was attended by Dr. Antal Nemeth, Chief Veterinary Officer, Dr. Barnabas Sas Executive Director, National Food Investigation Institute, Budapest, Dr. Imre Rayda, Deputy Director, National Food Investigating Institute, Dr. Sándor Tili, Head Export Department, Dr. Veronica Oláh, Senior Veterinary

Officer, National Food Investigation Institute, and FSIS auditor Dr. Suresh P. Singh, and Mr. F. Nemes, FAS/US Embassy. Topics of discussions included the following:

1. Audit itinerary and travel arrangements.
2. Use of nutritional or geographic claim labels.
3. SSOPs, HACCP, *Escherichia coli (E. coli)*, *Salmonella*, and *Listeria monocytogenes* testing.
4. National residue control program.
5. FSIS policy on 'listing and delisting' of establishments.
6. Compliance enforcement.

Hungary's inspection system officials stated that corrective measures had been initiated to prevent the recurrence of deficiencies noted during the previous FSIS audit in November 2000.

Headquarters Audit

There had been no organizational changes in Hungary's meat inspection systems. Some of the key officials include:

Dr. Antal Nemeth - Chief Veterinary Officer (CVO)
Dr. Laura Herpay - Deputy CVO
Dr. Ágnes Horváth - Head of Department of Food Control
Dr. Barnabas Sas - Executive Director, National Food Investigation Institute

To gain an accurate overview of the effectiveness of inspection controls, the FSIS auditor requested that the audits of the individual establishments be led by the inspection officials who normally conduct the periodic reviews for compliance with U.S. requirements. The FSIS auditor (hereinafter called "the auditor") observed and evaluated the process.

The auditor conducted a review of the inspection system documents pertaining to the establishments listed for site audit. The records review was conducted at the establishments and at the headquarters. The records review focused primarily on food safety hazards and included the following:

1. Organizational structure of Animal Health and Food Control Department.
2. New initiatives and regulatory changes (Act, regulations, and policy).
3. Internal review reports and monthly supervisory reports.
4. Food safety initiatives such as Sanitation Standards and Operating Procedures (SSOPs), pathogen reduction (PR) for generic *E. coli* testing, *Salmonella* species, and *Listeria monocytogenes* testing and Hazard Analysis and Critical Control Point (HACCP).
5. Performance standards for sanitation, facilities, and equipment including water potability and insect and rodent control, etc.
6. Slaughter and processing inspection procedures and standards including labels approval, boneless inspection, etc.
7. Label approval records.
8. Epidemiology and zoonotic trends in Hungary including control of products from livestock disease conditions.

9. National residue control program.
10. Enforcement records.

No concerns arose as a result of the examination of these documents.

Government Oversight

All inspection veterinarians and food inspectors in establishments certified by Hungary to export meat product to the United States were full-time or part-time employees receiving no remuneration directly from either industry or establishment personnel. All U.S.-certified establishments are provided continuous inspection.

In Hungary, there is an Animal Health and Food Control Station (Department) in each of 20 counties, and three veterinary institutes: Veterinary Diagnostic Central, National Food Investigating, and Veterinary Biologics, Drugs and Animal Foodstuffs. The Animal Health and Food Control Department, comprising of about 80 headquarters employees in Budapest, is managed by Dr. Antal Nemeth, Chief Veterinary Officer. Dr. Ágnes Horváth, Head of Department of Food Control, manages the national food/meat inspection programs in 20 counties. District Veterinary Directors in each of the 20 Stations supervise Animal Health and Food Control activities.

Each of the 20 county governments, in addition to the meat inspection, operate a laboratory staffed with technicians and professionals – chemists, veterinarians, agricultural engineers, veterinary and food inspectors. These laboratories provide support for animal health, food safety, pathological, microbiological and antibiotic, and animal feed testing.

The Central Veterinary Diagnostic Institute in Budapest coordinates animal health diagnostic and the residues control activities, and provides analytical confirmation and specialty support to 20 county laboratories.

Establishment Audits

Seven establishments (Ests. 5, 6, 7, 10, 24, 62, and 147) were certified to export meat products to the United States. All were visited for on-site audits. With the exceptions described in this report, generally the inspection and establishment system controls were in place to prevent, detect and control contamination and adulteration of the product.

Laboratory Audits

During the laboratory audit, emphasis was placed on the application of procedures and standards that were equivalent to the U.S. requirements. Information was also collected about the risk areas of government oversight of accredited, approved laboratories; intra-laboratory quality assurance procedures, including sample handling; and methodology.

The National Food Investigation Institute Laboratory in Budapest was audited on February 26, 2002. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and print outs, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

Hungary's microbiological testing for *Salmonella* was being performed in government laboratories. One of these, the National Food Investigation Institute Laboratory in Budapest was audited. The laboratory was well equipped and staffed with competent and qualified staff. It performs monitoring for microorganisms such as *E. coli*, *Salmonella* species, total plate counts, etc., food and meat products, food additives, animal feed stuffs and supplements, chlorinated hydrocarbons, trace elements, aflotoxins, mycotoxins, and microbiological and physico-chemical analysis of water.

Establishment Operations by Establishment Number

The following operations were being conducted in the seven establishments:
Establishment 5 – Cattle and swine slaughter, cutting, boning, curing/drying/smoking product.
Establishment 6 – Cattle and swine slaughter, cut up, boning, curing/drying/smoking, non-shelf stable product canning, and edible rendering.
Establishment 7 – Swine slaughter, cut up, boning, curing/drying/smoking, and edible rendering.
Establishment 10 – Swine slaughter, cut up, boning, curing/drying, smoking, and non-shelf stable product.
Establishment 24 – Cattle and swine slaughter, cut up, and boning.
Establishment 62 – Swine slaughter cutup, boning, curing/drying/smoking, and non-shelf stable product canning.
Establishment 147-Swine Boning, cutting, curing and smoking.

SANITATION CONTROLS

Based on the on-site audits of establishments, Hungary's inspection system had controls in place for water potability records; chlorination procedures, back-siphonage prevention; hand washing facilities; sanitizers; separation of operations; pest monitoring and control; temperature control; lighting; work space; dry storage areas; personal dress, habits, and hygiene; equipment sanitizing; and product storage.

Sanitation Standards Operating Procedures (SSOPs)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOPs were found to meet the basic FSIS regulatory requirements.

Cross-Contamination

- In Establishment. 5, there was no warm water supply in locker room because of mechanical problem and windows in locker area were not shut tight and there was potential for insects and flies.
- In Establishment 24, knife sanitizers in boning and cutting room were not maintained at 82 Centigrade temperature and cross contamination was observed on finished carcasses ready to enter in blast freezer due to dirty plastic flaps touching each carcass.
- In Establishment 62, condensation in carcass cooler was dripping, however not on carcasses; plastic containers in boning and cutting rooms were not identified for edible and inedible products.

ANIMAL DISEASE CONTROLS

Hungary's inspection system had controls in place to ensure adequate animal identification, antemortem and postmortem inspection procedures, carcass and parts disposition, and procedures for sanitary handling of product.

There were reported to have been no outbreaks of animal diseases with public heath significance since the previous U.S. audit.

RESIDUE CONTROLS

Hungary's National Residue Testing Plan for 2001 was being followed, and was on schedule. The Hungarian inspection system had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals.

SLAUGHTER/PROCESSING CONTROLS

The Hungarian inspection system had controls in place to ensure adequate animal identification; antemortem inspection procedures; antemortem disposition; humane slaughter; postmortem inspection procedures; postmortem disposition; restricted product control; boneless meat inspection; ingredient identification; control of restricted ingredients; formulations; packaging materials; inspector monitoring; processing schedules; processing equipment and records; empty inspection and filling procedures; container closure examination; post-processing handling; processing defect action-plant; and processing control-inspection.

HACCP Implementation

All establishments approved to export meat products to the U.S. were required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instruments used accompanies this report (Attachment B).

The HACCP program was found to meet basic FSIS regulatory requirements.

Testing for generic *E. coli*

Hungary has adopted the FSIS regulatory requirements for *E. coli* testing with the exception of the following equivalent different requirements:

1. LABORATORIES. Government laboratories.

    - The laboratories have properly trained personnel, suitable facilities and equipment, a written quality assurance program, and reporting and record keeping facilities.

    - Results of analyses including all permanently recorded data and summaries are reported promptly to the establishment.

Ests. 5, 6, 7, 10, 24, and 62 were required to meet basic FSIS regulatory requirements for *E. coli* testing and were audited and evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The *E. coli* testing programs were found to meet the basic FSIS regulatory requirements.

Additionally, establishments had adequate controls in place to prevent meat products intended for Hungarian domestic consumption from being commingled with products eligible for export to the U.S.

ENFORCEMENT CONTROLS

Inspection System Controls

The Hungarian inspection system controls (control of restricted products and inspection samples, boneless meat reinspection, shipment security, including shipment between establishments, prevention of commingling of product intended for export to the United States with domestic product, monitoring and verification of establishment programs and controls including taking and documentation of corrective action under HACCP plans), inspection supervision and documentation, the importation of only eligible livestock from other countries (only from eligible countries and certified establishments within those countries), and the importation of only eligible meat from other countries for further processing were in place and effective in ensuring that products produced by the establishment were wholesome, unadulterated, and properly labeled. In addition, adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* species

Six of the establishments audited (Ests. 5, 6, 7, 10, 24, and 62) were required to meet the basic FSIS regulatory requirements for *Salmonella* species testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

Hungary has adopted the FSIS regulatory requirements for *Salmonella* testing.

The *Salmonella* testing programs were found to meet the basic FSIS regulatory requirements.

The inspection service collected samples. In the case of a positive result, product is identified, re-called if available, and confiscated for further action. Future shipments are withheld subject to laboratory analyses clearance. Investigation is conducted to determine root-cause(s) of product adulteration.

Testing for *Listeria monocytogenes*

One sample was collected each month from ready to eat products and one sample from each export shipment of all ready-to-eat products. The *Listeria* adulteration and positive result from sampling of paprika salami at the port of entry in the United States in the month of January from Establishment 7 was discussed at the exit meeting. GOH officials assured that corrective actions will be taken and investigation will be done and will be reported to International policy at Washington.

Species Verification Testing

At the time of this audit, Hungary was not exempt from species verification-testing requirement. The auditor verified that species verification testing was being conducted in accordance with FSIS requirements.

Monthly Reviews

These reviews were being performed by the Hungarian equivalent of Area Supervisors. All were veterinarians with at least 10 years of experience.

The internal review program was applied to all exporting establishments. Internal review visits were announced in advance and were conducted at least once monthly. The records of audited establishments were kept in the inspection offices of individual establishments, and copies were also kept in county office, and were routinely maintained on file for a minimum of 2 years.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again qualify

for eligibility to be reinstated, a team with Head, Food Inspection, of National Food Investigation Institute is empowered to conduct in- depth review, and results are reported to Chief Veterinary Officer of Hungarian Government for evaluation. They formulate a plan for corrective action and preventive measures.

Enforcement Activities

Each county Station's field Veterinary Staff Officers are authorized to provide livestock transportation certificates, verify withdrawal of drugs before slaughter, monitor and control additives and regulated drugs administration to the livestock and use in feed stuffs, monitor rendering facilities, and investigate violations of residue and other regulatory requirement. Violations are reported to police for legal action. Violators could be fined up to Fr 1,000,000. The compliance enforcement action pertaining to product confiscation, fines, and imprisonment are legislated.

Exit Meeting

An exit meeting was conducted in Budapest on February 28, 2002. The Hungarian participants were, Dr. Ágnes Horváth; Head Food Control Department; Dr. Imre Rayda, Head National Food Investigating Institute, Dr. Sándor Tili, Head Export Department, Dr. Veronica Oláh, Senior Veterinary Officer, National Food Investigation Institute, and Dr. Suresh P. Singh, International Audit Staff Officer, TSC-FSIS-USDA.
The following topics were discussed:

1. Observations and findings in Establishments 5, 24 and 62 were discussed as reported in the cross-contamination section of this report. Hungarian officials took immediate corrective action during the review of each establishment.
2. Inspection service would evaluate and investigate for *Listeria monocytogenes* in Establishment 7 as the letter from International Policy in Washington requested.
3. Official guidelines would be issued on how to deal with situations when positive cases of *Listeria* were recorded.
4. Mechanical Deboning (319.5) requirements were discussed as requested by Hungarian Officials.

CONCLUSION

The inspection system of Hungary was found to have effective controls to ensure that products destined for export to the United States were produced under conditions equivalent to those that FSIS requires in domestic establishments. Seven establishments were audited and all were acceptable. The deficiencies encountered during on-site establishment audits were adequately and immediately addressed to the auditor's satisfaction.

Suresh P. Singh, DVM, Ph.D. (Signed)*Suresh P. Singh, DVM, Ph.D.*
International Audit Staff Officer

ATTACHMENTS

A. Data collection instrument for SSOPs
B. Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory Audits Forms.
F. Individual Foreign Establishment Audit Forms.
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOPs

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOPs were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of the establishments visited on-site were evaluated as follows:

Est. No.	1.Written program addressed	2. Pre-op sanitation addressed	3. Operational sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6.Responsible individual Identified	7.Documenta-tion done daily	8. Dated and signed
5	√	√	√	√	√	√	√	√
6	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment had conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. No	1.Flow diagram	2.Hazard analysis done	3. All hazards identi-fied	4. Use and users included.	5. Plan for each hazard	6. CCPs for all hazards	7.Monit. critical limits, and freq. specified	8.Correc-tive actions described	9. Plan validated	10. Adeq. Verific. Proc.	11. Adeq. Docum.	12. dated and Signed
5	√	√	√	√	√	√	√	√	√	√	√	√
6	√	√	√	√	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√	√	√
147	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data collection instrument for Generic *E. coli* Testing

Each establishment (except Est. 147) was evaluated to determine if the basic FSIS regulatory requirements for generic E. coli testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli*.
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

The results of these evaluations were as follows:

Est. No.	1. Written procedure	2. Sample collector designated	3.Sampling location given	4.Predomi-nant spp. sampled	5.Sampling at required frequency	6.Proper site or method	7.Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
5	√	√	√	√	√	√	√	√	√	
6	√	√	√	√	√	√	√	√	√	√
7	√	√	√	√	√	√	√	√	√	√
10	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√
24	√	√	√	√	√	√	√	√	√	√
62	√	√	√	√	√	√	√	√	√	√

Attachment D

Data Collection instrument for *Salmonella* testing

Each slaughter establishments were evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.
2. Carcasses are being sampled.
3. Ground product is being sampled.
4. The samples are being taken randomly.
5. The proper carcass site(s) and/or collection of proper product (carcass or ground) are being used for sampling.
6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. No.	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper production	7.Violative Est. stop operations
5	√	√	NA	√	√	√
6	√	√	NA	√	√	√
7	√	√	NA	√	√	√
10	√	√	NA	√	√	√
24	√	√	NA	√	√	√
24	√	√	NA	√	√	√
62	√	√	NA	√	√	√